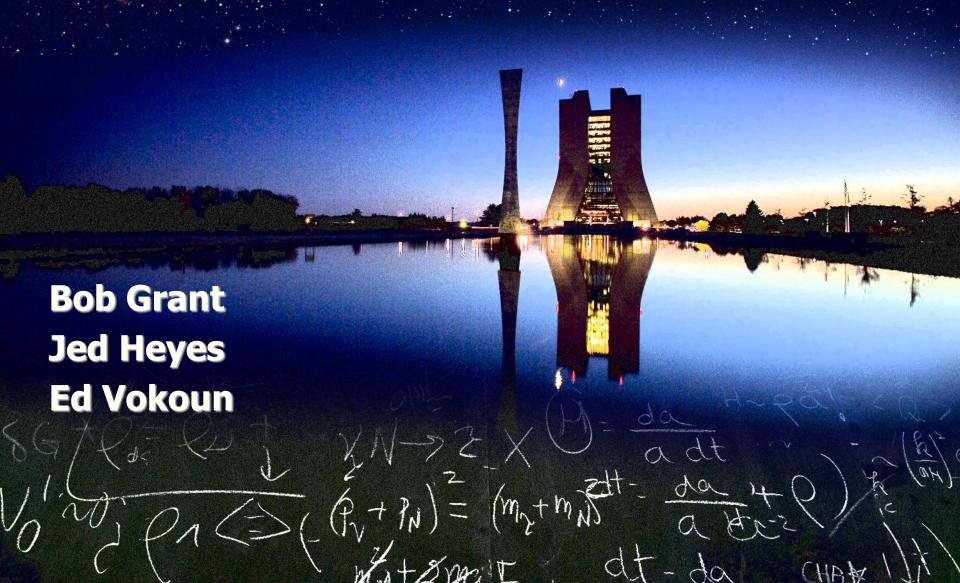
IQA & CA Implementation July 14, 2011



IQA Implementation Status

Quality Assurance Program Implementation



QA Implementation Status

- Scientific Research Projects
- Assessment Program
 - OQBP QA assessment schedule
 - Consolidated assessment schedule
 - Corrective Action Plan tracking
- Other activities & challenges



QA Implementation - Project QA Status

- Science / Project QA
 - Presentation on QA to management & project teams
 - Head of OPPS, AD Research, AD Accelerator
 - MicroBooNe Working Group Meeting
 - Working with PPD QAR on QA Plans (Minerva, MicroBooNe & Mu2e)
 - Assisting with CD-x Director's & Lehman review readiness QAPs
 - Developing templates, make available to L1, L2 project managers
 - MicroBooNE Cryogenic Engineering QA Plan module , larger QA template
 - Draft QA in projects presentation for project teams tbd
 - Attending PMGs, WGMs (APUL, DES, LBNE, NoVA, Project X, MicroBooNe & Mu2e)
 - Assessments completed (As-Is, Scientific Publications, EVMS) more planned



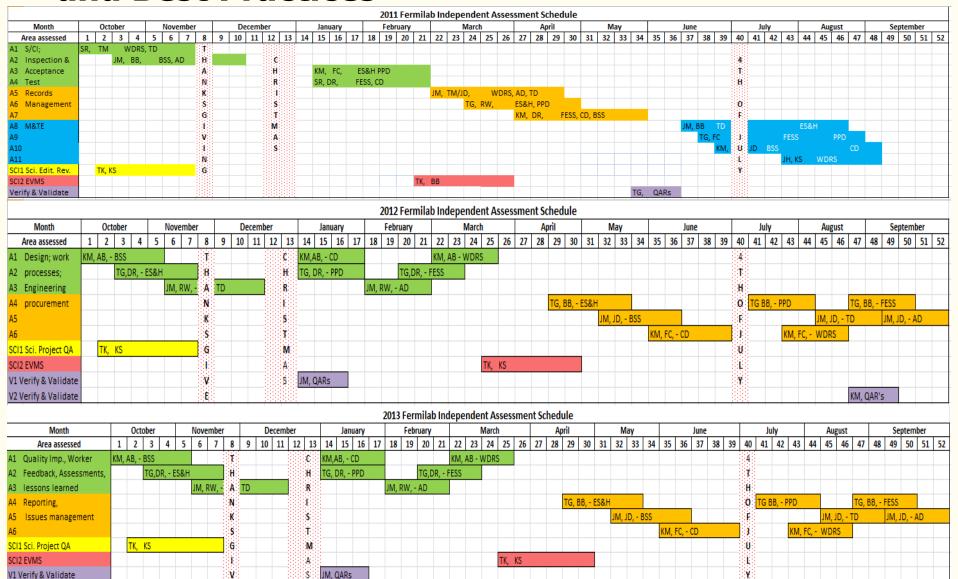
QA Implementation Status - Assessments, Schedule

- OQBP QA Assessments
 - FY2010 process based D/S/C & OQBP selected
 - FY2011-2013 3 year approach
 - IQA criteria based, lab-wide
 - Includes scientific research, projects & support
 - Individual & summary roll up reports by criteria
 - Flexibility based on D/S/C staff, activities, QAR & QAE availability etc
 - » Accommodate requests ex: order of 2012 from D/S/Cs
 - » Regular progress meetings issues, lessons etc QAE meeting, & QAR meetings
 - CAS requirements as program matures -> 2013
 - FY2014 return to process based D/S/C & OQBP selected assessments
 - Most value to D/S/Cs & most relevant QA criteria

V2 Verify & Validate

3 Year OQBP Assessment Schedule

KM, QAR's



Assessment Program – Fermilab Consolidated 3 Year Schedule

- Fermilab Consolidated Assessment 3 year schedule
 - All assessment types FY2010-FY2012
 - Categories of assessment types available to track
 - Management Assessments
 - Independent Assessments (OQBP, ES&H, Third-party such as DOE, ISO, etc)
 - Inspections (HPR, Walkthroughs etc)
 - Drills
 - Surveillances
 - Director's Assessments
 - Special Assessments (for cause)
 - ... Others mentioned in FAM Chapter 2 Appendix
- ♦ 2010 lists complete, maintenance ongoing, coordinating with QARs
 - Await directive to staff from Sr. Management for 2011-2013
- Fermi Research Alliance

QAE staff reduced

QA Assessment Status

- OQBP Assessment Status at a Glance
 - ❖ FY2011 -
 - S/CI inspection & test all D/S/Cs Q1, Q2 individual reports complete, lab-wide roll up summary in progress
 - Scientific Tech Publ / editorial review Q1 report delivered
 - EVMS surveillance Q2 final report delivered
 - Records management Q2, Q3 reports delivered
 - Roll up in progress
 - OQBP V&V for closed assessment CAPs all D/S/Cs Q3 reports in review
 - No issues found
 - M&TE all D/S/Cs 2 Large x-cutting Q3, Q4 in progress



QA Assessment Results to Date

- OQBP Assessment FY2011 Results at a Glance
 - ❖ Inspection & test all D/S/Cs Q1, Q2 3 Findings
 - 2 segregation of nonconforming material
 - 1 inspection documentation
 - ❖ S/CI 6 Findings

Fermi

- Not fully implemented (awareness, following procedures)
- ❖ M&TE 2 Findings to date
- 20 Observations with recommendations for improvement
 - Documentation & records, infrastructure, work control, etc

Science / Project QA Assessment Status

- Science / Project QA Assessments & Status
 - Science As-Is baseline final report delivered to AD for Research
 - No CAPs
 - Program, & Projects (Minerva, MINOS, Muon Accelerator, D0, Lattice QCD)
 - Scientific Publication final report delivered to AD for Research
 - One CAP
 - 14% of publications assessed non-compliant
 - EVMS NoVA - final report delivered to Head, OPMO
 - 8 CARs, 5 CIOs re EVMS & ANSI compliance



QA Implementation - CAPs

- Corrective & Preventive Action tracking
 - DOE 2006 QA assessment
 - DOE 2009 QA assessment
 - OQBP led assessments (includes 2009 As-Is)
 - Ad hoc tracking improvement initiatives (ex: training)



2009 DOE QA Concerns - CAP Status

- ♦ 4 New CAPs OQ-01/04/2010-01 thru -04
 - ❖ C1 & C2 Terms used in CAPA procedure OQ-01/04/2010-01 complete
 - ❖ C3 WSS/FESHM 1070 maintenance roles OQ-01/04/2010-03 complete
 - C6 Documentation of acceptance testing varies OQ-01/04/2010-04
 - Inspection assessment report delivered to FSO complete
 - ❖ C7 & C8 Identify assessment criteria, define terms OQ-01/04/2010-02
 - C7 FAM Mgmt. Assess. Procedure updated & posted complete
 - C8 Other FAM updates from 2009 assessment complete
 - Manual revised to incorporate H13 Clause requirements complete
 - Independent Assess. Procedure updated & posted complete
 - Lab-wide review complete, next review ES&H/OQBP taskforce



2009 DOE QA Concerns — CAP Status

- Existing As-Is CAPs
 - ❖ C5 Fermilab Chief Engineer OQ-05/22/2009-01 IQA being modified, Integrated into new Office of Program & Project Support (OPPS)
 - OQBP, OPMO, new Office of Integrated Planning (OIP)
 - Planning & support, EVMS, OHAP, Engineering Manual
 - C4 & SC1 (sig. concern) Inconsistent engineering practices, lack of Engineering Manual – OQ-05/22/2009-02 – complete
 - ❖ C9 & C10 S/CI roles & disposition OQ-05/30/2009-06 complete
 - Other activities
 - S/CI Tags in inventory, Collected training samples, Training to be updated
 - FESHM update planned to reference the new tag
 - S/CI assessment along with Inspection & Test renewed awareness



2009 DOE QA Concerns — 4 CAPs from 2006 DOE QA assessment

- ❖ Criterion 2 Job specific training ITNAs OQ-08/10/2009-01 09/31/2011
 - Initial system enhancements & testing complete more in progress
- Criterion 4 Document management OQ-08/05/2009-01(a, b & c)
 - (a) EDMS (Teamcenter) est. completion MM/DD/YY
 - (b) CIO IT (Sharepoint) est. completion MM/DD/YY
 - (c) COO (policy, process) est. completion MM/DD/YY
- Criterion 4 Records management OQ-08/05/2009-02 complete
 - Handbook, procedures, training complete 01/19/10
 - Lab-wide assessment complete
 - summary rollup in progress
- Criterion 8 Calibration AD-05/07/2009-03 complete



IQA Implementation

Other QA Activities



QA Implementation – Other Activities

- Improved Integration with ES&H Management System
 - ES&H/OQBP task force (SSOs & QA Mgr)
 - Updating FESHM chapters & QA RCA & CAPA procedures
 - Next Fermilab Assessment Manual (FAM)
- ♦ New Online Assessment Program Training tbd from above
 - Draft created
 - QAR subteam created FAQ's, posted on OQBP website
- ♦ Improved S/CI Online Training tbd



IQA Implementation

Quality Assurance Program Challenges



QA Implementation - Challenges

- ♦ Software, frESHTRK versus Vector Reported to CIO -> Sharepoint
 - Working on Sharepoint test server, await production site
- Graded Approach
 - COO considering alternatives
- ♦ Timely implementation of some CAPs
- Maintenance of consolidated schedule resources
- ♦ Aggressive QA assessment schedule partially mitigated 2012-2013
- ◆ QAR turnover (TD reassigned, ES&H retired, PPD?)



QAEs

- FSO OQBP Joint Activities
 - Next quarterly IQA brief mid Oct 2011
 - ❖ Next FSO DOE QA assessment Q4 FY2012
 - HSS versus FSO DOE O 414.1D versus O 414.1C
 - Logistics, criteria, scope, impact 414.1D etc
 - Other meetings?
 - SMART database QA items tbd



IQA Implementation

Questions?



CA Implementation

Contractor Assurance Implementation Status



Contractor Assurance Short Term Upcoming Events

- ♦ FRA CAS Steering Committee Assessment June 12-15, 2011
 - Results not positive
 - New Task force convened by Pier, Chair Bob Kephart
 - QA Management System inputs delivered (model for others?)
 - OQBP continues to provide work products as requested

♦ DOE Peer Review of Contractor Assurance Program – August 2011



CA Implementation

Questions?

